Specific Diagnostics Announces US Clinical Trials for its Reveal Rapid Antibiotic Susceptibility Testing (AST) System

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Specific Diagnostics announces today that its US clinical studies for Reveal Rapid AST System will commence at the beginning of August, and entail 3 months of data collection, followed by submission for FDA consideration of 510(k) clearance of the Reveal test. Reveal determines bacterial susceptibility of blood infections to antimicrobial drugs in an average of 5 hours, allowing same-shift adjustment of treatment, saving lives while reducing costs and improving the utilization of antibiotics. Reveal is already on-market in Europe under CE-IVD registration, and upon clearance Reveal will be only the second Rapid AST platform approved for use in the United States.

While rapid identification (ID) instrumentation for blood stream infections is now widely used in US, clinicians often wait 2 days to receive the AST results required to identify the correct antibiotic therapy, which the ID result alone does not enable. This delay results in overuse of costly broad spectrum, empiric antibiotic therapy, and can put patient lives at risk. Same-day AST results lead to either timely de-escalation to a focused and lower-cost therapy, eliminating harmful disruption of the microbiome, or immediate escalation to a drug of last resort in the increasingly prevalent case where multi drug resistant (MDR) infection is present, saving a life.

Reveal's low cost, high throughput, broad menu, and small footprint are all suited to wide-spread adoption. Modular system design ensures no single point of failure, 100% uptime, and incremental adoption by hospitals of any size. The unique Reveal Dashboard™ provides the lab easy-to-use realtime tools to monitor trends of infection and resistance as well as instrument performance.

"Same-shift AST fills a major gap in the timely treatment of blood stream infections, and we are pleased to be among the distinguished laboratories chosen to conduct FDA trials for this instrument," agreed Dr. Linoj Samuel, Division Head of the Clinical Microbiology Laboratory of the Henry Ford Hospital in Detroit. "Our Reveal preclinical study, now being readied for submission, will report both a high level of accuracy and rapidity for the Reveal System, and we look forward to participating in the larger scale clinical study soon underway."

"We are honored that 6 of the most distinguished institutions in the country have agreed to join Specific in the validation of the Reveal system for use in the United States," said Dr. Paul A. Rhodes, Specific's CEO. "Their knowledge and experience in the clinical trial process will ensure expert and credible assessment of the performance of the Reveal instrument, which is already on-market in Europe. We are glad to have the opportunity to work with them to bring this life-saving instrument to the US."

About Specific

Specific Diagnostics has developed in vitro diagnostic systems based upon a unique, patented metabolomic signature technology that enables rapid detection and identification of microorganisms as they grow in culture. Its first commercial application applies this fundamental new capability to the rapid determination of antimicrobial susceptibility directly from positive blood cultures, as well as isolate dilutions. Specific is based in Mountain View, CA.

For press inquiries, please contact: press@specificdx.com